

not be considered further. Finally, this brief description of polymer primary structure (the chain makeup) did not consider graft polymers (where monomer and polymer side chains are attached as pendent groups to the primary polymer chain) or crosslinking between chains and/or pendent groups (secondary polymer structure). However, any and all of the primary and secondary structures discussed herein and variations thereon are considered within the scope of the present invention.

**Please replace paragraph [0095] beginning at page 27, line 26, with the following amended paragraph:**

Swellability is also an important factor. Polymer free volume increases proportionally to increases in swellability. Therefore, drug elution rate, ~~as well as Tg~~ increases with increasing swellability. As a result, for the purposes of the present invention the total swellability of the polymer blend used with bioactive agents having molecular weights less or than about 1200 g/mol and polymer blends having a  $\delta_T$  greater than  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$  should not exceed 10% by volume. Moreover, the total swellability should not exceed 10% by volume when the active agents have molecular weights greater than about 1200 g/mol and the polymer blend has a  $\delta_T$  less than  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$ . In both cases this remains true regardless of whether the bioactive agent is hydrophilic or hydrophobic.

**Please replace paragraph [0102] beginning at page 30, line 16, with the following amended paragraph:**

Furthermore, in one embodiment of the present invention compatible polymer blends are made wherein the ratio of low Tg polymer to high Tg polymer is in the range of 20:80 to 80:20. In one particular embodiment the ratio of low Tg polymer to high Tg polymer is 50:50. In another embodiment the ~~ratio~~ ratio of low Tg polymer to high Tg polymer is 60:40. In another embodiment the ~~ratio~~ ratio of low Tg polymer to high Tg polymer is 70:30. In another embodiment the ~~ratio~~ ratio of low Tg polymer to high Tg polymer is 80:20. It is understood that these ratios and ranges are approximate and that

the exact ratio of low Tg polymer to high Tg polymer is determined in accordance with the present teachings.

**Please replace paragraph [0106] beginning at page 32, line 33, with the following amended paragraph:**

Table 2 represents the exemplary polymer blend prepared in accordance with the teachings of the preset invention and the resulting  $\delta_T$  value for each polymer blend. The blends were prepared such that the resulting  $\delta_T$  fell between 15 and 21  $\delta$  to be compatible with drugs'  $\delta$  of 17.5.

TABLE 2  
EXEMPLARY COMPATIBILIZED CONTROLLED RELEASE COATINGS

Compatibilized Polymer Blend	<del>Percent Monomer</del> Sub-unit Component <sup>1</sup> Weight percent of polymers <sup>1</sup>	Polymer Blend ID	$\delta_T$
PEVAc:Polymer A	50/50	I	17.7
PEVAc:Polymer A	60/40	II	17.8
PEVAc:Polymer B	50/50	III	17.8
PEVAc:Polymer B	40/60	IV	17.8
PEVAc:Polymer B:Polymer C	40/50/10	V	17.9
PEVAc:Polymer B:Polymer C	40/40/20	VI	18.0
PEVAc:Polymer B:Polymer C	50/41.7/8.3	VII	17.8
PEVAc:Polymer B:Polymer C	50/33.3/16.7	VIII	17.9
PEVAc:Polymer B:Polymer C	60/33.3/6.7	IX	17.8
PEVAc:Polymer B:Polymer C	60/26.7/13.3	X	17.8
PEVAc:Polymer E	20/80	XI	20.2
Polymer B: Polymer D1	80/20	XII	18.0
Polymer B: Polymer D1	70/30	XIII	18.0
Polymer B: Polymer D1	60/40	XIV	18.0
Polymer B: Polymer D1	50/50	XV	18.0

<sup>1</sup> The percent ~~monomer sub-unit~~ polymer component is measured on a weight-percent basis.

Polymer B: Polymer D1	40/60	XVI	18.0
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#### EXAMPLE 1 A

#### General Method of the Two-Step Synthesis of Segmented n-Butyl Methacrylate and Vinyl Acetate Copolymers

**Amendment to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claim 1 (Currently Amended): A medical device comprising a controlled release coating for an implantable medical device comprising:

a terpolymer-bipolymer blend having a total solubility parameter ( $\delta_T$ ) approximately equal to a bioactive agent's solubility parameter ( $\delta$ ) and wherein  $\delta_T$  and  $\delta$  is between  $15 \text{ J}^{1/2}/\text{cm}^{3/2}$  to  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$ , wherein the terpolymer and bipolymer each include vinyl acetate and an alkyl methacrylate.

Claim 2 (Currently Amended): The ~~controlled release coating~~ medical device according to claim 1 wherein said coating has a glass transition point ( $T_g$ ) between approximately  $-20^\circ\text{C}$  and  $50^\circ\text{C}$ .

Claim 3 (Currently Amended): The ~~controlled release coating~~ medical device according to claim 1 wherein said terpolymer comprises ~~relative weight percent concentrations of~~ monomer subunits consisting of vinyl acetate (VAc), alkyl methacrylate (AMA) and n-vinyl pyrrolidone (NVP) and said bipolymer comprises ~~relative weight percent concentrations of~~ monomer subunits consisting of VAc and AMA.

Claim 4 (Currently Amended): The ~~controlled release coating~~ medical device according to claim 3 wherein said relative ~~[[weight]]~~ mole percent concentrations of said monomer subunits in said terpolymer comprises ~~[[from]]~~ 7-30% (VAc), ~~[[40-74%]]~~ 40-75% (AMA) and 19-30% (NVP).

Claim 5 (Currently Amended): The ~~controlled release coating~~ medical device according to claim 3 wherein said relative ~~[[weight]]~~ mole percent concentrations of said monomer subunits in said bipolymer comprises ~~[[from]]~~ 5-70% VAc and ~~[[from]]~~ 30-95% AMA.

Claim 6 (Currently Amended): The ~~controlled-release-coating~~ medical device according to claim 3 wherein said alkyl of said alkyl methacrylate is selected from the group consisting of methyl, ethyl, propyl, butyl, pentyl, and hexyl.

Claim 7 (Currently Amended): The ~~controlled-release-coating~~ medical device according to any one of claims 1 through 6 wherein said  $\delta_T$  is approximately 15 to 21 and said polymer blend comprises from 40% to 80% bipolymer and from 20% to 60% terpolymer.

Claim 8 (Currently Amended): The ~~controlled-release-coating~~ medical device according to any one of claims 1-6 wherein said bipolymer has a lower Tg than said terpolymer.

Claim 9 (Currently Amended): The ~~controlled-release-coating~~ medical device according to claim 1 wherein said bioactive agent is selected from the group consisting of anti-proliferatives including, but not limited to, macrolide antibiotics, FKBP 12 binding compounds, estrogens, chaperone inhibitors, protease inhibitors, protein-tyrosine kinase inhibitors, peroxisome proliferator-activated receptor gamma ligands (PPAR $\gamma$ ), hypothemycin, nitric oxide, bisphosphonates, epidermal growth factor inhibitors, antibodies, antibiotics, proteasome inhibitors anti-sense nucleotides and transforming nucleic acids.

Claim 10 (Currently Amended): The ~~controlled-release-coating~~ medical device according to claim 9 wherein said antiproliferative is a FKBP 12 binding compound.

Claim 11 (Currently Amended): The ~~controlled-release-coating~~ medical device according to claim 10 wherein said FKBP 12 binding compound is a macrolide antibiotic.

Claim 12 (Currently Amended): The ~~controlled-release-coating~~ medical device according to claim 11 wherein said macrolide antibiotic is rapamycin or everolimus.

Claim 13 (Currently Amended): A vascular stent comprising:  
a structure comprising a material, said material having a coating thereon comprised of a hydrophobic polymer;  
a bioactive agent-containing terpolymer-bipolymer blend over said hydrophobic polymer wherein the difference between the solubility parameters of said terpolymer-bipolymer blend and said bioactive agent is no greater than  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$  and the total solubility parameter ( $\delta_T$ ) of said bioactive agent-containing terpolymer-bipolymer blend is no greater than  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$ , wherein the terpolymer and bipolymer each include vinyl acetate and an alkyl methacrylate.

Claim 14 (Previously Presented): The vascular stent according to claim 13 wherein said hydrophobic polymer is parylene.

Claim 15 (Currently Amended): The vascular stent according to claim 13 wherein said terpolymer comprises ~~relative weight percent concentrations~~ of monomer subunits consisting of vinyl acetate (VAc), alkyl methacrylate (AMA) and n-vinyl pyrrolidone (NVP) and said bipolymer comprises ~~relative weight percent concentrations~~ of monomer subunits consisting of VAc and AMA.

Claim 16 (Currently Amended): The vascular stent according to claim 15 wherein said relative ~~[[weight]]~~ mole percent concentrations of said monomer subunits in said terpolymer comprises ~~[[from]] 7-30% (VAc), [[40-74%]]~~ 40-75% (AMA) and 19-30% (NVP).

Claim 17 (Currently Amended): The vascular stent according to claim 13 wherein said relative ~~[[weight]]~~ mole percent concentrations of said monomer subunits in said bipolymer comprises ~~[[from]] 5-70% VAc and [[from]] 30-95% AMA.~~

Claim 18 (Previously Presented): The vascular stent according to claim 15 wherein said alkyl of said alkyl methacrylate is selected from the group consisting of methyl, ethyl, propyl, butyl, pentyl, and hexyl.

Claim 19 (Previously Presented): The vascular stent according to any one of claims 13 through 18 wherein said  $\delta T$  is approximately 15 to 21 and said polymer blend comprises from 40% to 80% bipolymer and from 20% to 60% terpolymer.

Claim 20 (Previously Presented): The vascular stent according to any one of claims 13-18 wherein said bipolymer has a lower Tg than said terpolymer.

Claim 21 (Previously Presented): The vascular stent according to claim 13 wherein said bioactive agent is selected from the group consisting of anti-proliferatives including, but not limited to, macrolide antibiotics, FKBP 12 binding compounds, estrogens, chaperone inhibitors, protease inhibitors, protein-tyrosine kinase inhibitors, peroxisome proliferator-activated receptor gamma ligands (PPAR $\gamma$ ), hypothemycin, nitric oxide, bisphosphonates, epidermal growth factor inhibitors, antibodies, antibiotics, proteasome inhibitors anti-sense nucleotides and transforming nucleic acids.

Claim 22 (Previously Presented): The vascular stent according to claim 21 wherein said antiproliferative is a FKBP 12 binding compound.

Claim 23 (Previously Presented): The vascular stent according to claim 22 wherein said FKBP 12 binding compound is a macrolide antibiotic.

Claim 24 (Previously Presented): The vascular stent according to claim 23 wherein said macrolide antibiotic is rapamycin or everolimus.